



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/697,351

10/29/2003

Kenneth F. Buechler

071949-1328

7522

30542

7590

08/17/2007

FOLEY & LARDNER LLP

P.O. BOX 80278

SAN DIEGO, CA 92138-0278

EXAMINER

ALEXANDER, LYLE

ART UNIT

PAPER NUMBER

1743

MAIL DATE

DELIVERY MODE

08/17/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

---

Commissioner for Patents  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

MAILED  
AUG 17 2007  
GROUP 1700

**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/697,351  
Filing Date: October 29, 2003  
Appellant(s): BUECHLER, KENNETH F.

Mr. Richard Warburg

For Appellant

**EXAMINER'S ANSWER**

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief

This is in response to the appeal brief filed 4/25/07 appealing from the Office action mailed 10/25/06.

**(2) Related Appeals and Interferences**

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

09/613,650

10/153,423

10/697,351

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**GROUND OF REJECTION NOT ON REVIEW**

The following grounds of rejection have not been withdrawn by the examiner, but they are not under review on appeal because they have not been presented for review

in the appellant's brief. The provisional rejection of claims 1 and 3-7 under the judicially created doctrine of obviousness-type of double patenting over copending application 11/022,297 and 10/792,258.

### **NEW GROUND(S) OF REJECTION**

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Findlay et al. or Wu et al. in view of Oosta et al.(USP 5,478,751).

#### **(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

#### **(8) Evidence Relied Upon**

5,514,550	Findlay et al.	5-1996
5,387,510	Wu et al.	2-1995
5,478,751	Oosta et al.	12-1995

#### **(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 and 1-24 of copending Application No. 11/022, 297 and 10/792,258 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because all are directed to an assay device for detecting one or more ligands.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is confusing what structure is contemplated by the claimed second surface and how it interacts with the nonporous surface.

Claim 7 is vague and indefinite the meets and bounds of the claim. No structure is claimed that further limits the subject matter of any one of the previous claims 1-5. Apparently, this claim is directed to claiming the absence of a structure (e.g. absence of a capillary space) and is not readily understood.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5 and 7 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Findlay et al. (USP 5,514,550) or Wu (USP 5,387,510).

In light of the above 35 USC 112 issues, the claims are best understood as a nonporous surface with immobilized particles that have binding receptors.

The effective filing date of this application has been determined as 7/11/00 because the parent patents 6,156,270, 6,143,576 and 6,271,040 does not contain the presently claimed “nonporous” surface.

Findlay et al. teach an assay device having a nonporous surface (see col. 14 lines 9+) with particles immobilized to the surface. Column 6 lines 31-41 teach the particles are in the range of 0.1-10 microns and preferably between 0.1 and 5 microns (also see claim 3). The claimed protrusions extending between 1 microns to 0.5mm has been read on the taught immobilized particles. Column 6 lines 41-55 teach the claimed materials of the particles. Example 2 in column 13 expressly teaches the particles are made of polystyrene. The surface of Findlay et al. would have been expected to have at least one depression/protrusion between 1nm and 0.5mm as a manufacturing imperfection. The Office has read this on claim 3 “... a textured surface comprising one or more depressions and/or protrusion extending between 1nm and 0.5mm... “.

Wu teaches a nucleic acid amplification kit. Column 10 lines 47-64 teach the surface can be nonporous. Column 9 lines 3-9 teach the particles immobilized on the surface could be from 0.01-10 microns. Column 9 lines 38-50 teach the particles can be made of polystyrene. The claimed protrusions extending between 1 microns to 0.5mm has been read on the taught immobilized particles. The surface of Wu et al. would have been expected to have at least one depression/protrusion between 1nm and 0.5mm as a manufacturing imperfection. The Office has read this on claim 3 "... a textured surface comprising one or more depressions and/or protrusion extending between 1nm and 0.5mm...".

#### **NEW GROUND(S) OF REJECTION**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Findlay et al. or Wu et al. in view of Oosta et al.(USP 5,478,751)

See Findlay et al. and Wu et al. supra.

These references are silent to placing a second surface at a capillary distance from the nonporous surface.

Oosta et al. teach an immunodiagnostic device that binds target ligands. In column 7 lines 20-38, Oosta et al. teaches a cover on the device to protect the binding reagents. Additionally, column 6 lines 37-55 teach the device is a capillary flow device and all of the dimensions are such to promote capillary flow. In light of the teachings of column 6, the Office has read Oosta et al. as teaching the cover taught in column 7 is spaced "... at a capillary forming distance ..." as presently claimed.

It would have been within the skill of the art to modify Findlay et al. or Wu et al. and provide a second surface, at a capillary forming distance, to protect the binding reagents.

#### **(10) Response to Argument**

Appellant's 1/25/07 terminal disclaimers have obviated the obviousness type of double patenting rejections made in the 10/25/06.

Appellant acknowledges the provisionally rejected claims under the judicially created doctrine of obviousness-type double patenting over copending application 10/792,258 and 11/022,297 are not being appealed.

(1.) Appellant remarks that one having ordinary skill in the art would have understood the claim language of "nonporous surface" has been convincing. Additionally, the remarks that one having ordinary skill in the art would have understood the claimed "particle size range is from 1nm to 5 microns" as referencing the diameter



of the particles has also been convincing. The Office will vacate this component of the 35 USC 112 second paragraph rejections.

(2.) Appellant traverses the 35 USC 112-second paragraph rejection of claim 6. Appellant states the second surface is one other than the nonporous surface. This does not positively describe the intended structure of the second surface.

(3.) Appellant traverses the 35 USC 112-second paragraph rejection of claim 7. Appellant states the use of a negative limitation in this claim is proper. The Office maintains it is not clear how the nonporous surface is not part of the capillary space because the claims do not adequately describe how the nonporous surface interacts with the second surface. This claim does not positively describe the intended structure of the nonporous surface that interacts with the second surface such that it is not part of the capillary space.

(4.) Appellant states Findlay et al. teach detection of a target ligand and cannot be read on the claimed use of "antibodies or fragments thereof capable of binding one or more target ligands". Initially, the Office notes both Findlay et al. and the instant invention are directed to the detection of "target ligand" by Appellant's own admission. Appellant also states Findlay et al. does teach in column 7 lines 23-27 the use of antibodies as part of the target ligand detection. Appellant states Findlay et al. differ from the instant invention by the specific use of the antibody to detect the target ligand. These remarks are not commensurate in scope with the pending claims. The instant claims do not exclude additional elements that could be used in combination with the

antibodies to determine the target ligand. The Office maintains Findlay et al. teach use of antibodies to detect a target ligand and clearly anticipates claim 1.

Appellant has not put forth any argument traversing the individual limitations of claims 5 and 7. The Office maintains Findlay et al. clearly anticipates claims 5 and 7 for the reasons set forth above.

(5.) Appellant states Findlay et al. does not teach the claimed “depressions and/or protrusions”. Claim 3 “... said surface is a textured surface comprising one or more depressions and/or protrusions extending between 1 nm and 0.5mm from the surface”. The Office takes the position the nonporous surface taught by Findlay et al. would have been expected to have **at least one depression or protrusion** from the surface in the claimed range of 1nm to 0.5mm as an artefact of the manufacturing process. The Office maintains Findlay et al. clearly anticipated pending claim 3.

(6.) Appellant states Findlay et al. does not teach the claimed “... one or more of said particles are entrapped within depressions and/or between protrusions on the textured surface”. As stated above, the Office expects the nonporous surface taught by Findlay et al. to have at least one manufacturing artefact that clearly anticipates claim 3. Findlay et al. teaches binding particles to the surface as discussed above. It would have been expected for at least one particle to be bound on the artefact. Findlay et al. clearly anticipates claim 4.

(7.) Appellant states Findlay and Wu et al. fail to teach the limitations of claim 6 “... a second surface spaced at a capillary forming distance from said non-porous

Art Unit: 1743

surface". The Office has addressed this issue in the new grounds of rejection under 35 USC 103.

(8.) Appellant states Wu et al., like Findlay et al., teach detection of a target ligand and cannot be read on the claimed use of "antibodies or fragments thereof capable of binding one or more target ligands". The Office notes both Wu et al. and the instant invention are directed to the detection of "target ligand" by Appellant's own admission. Wu et al. teach in column 11 lines 45-47 the use of antibodies as part of the target ligand detection. Appellant states Wu et al. differ from the instant invention by the specific use of the antibody to detect the target ligand. These remarks are not commensurate in scope with the pending claims. The instant claims do not exclude additional elements that could be used in combination with the antibodies to determine the target ligand. The Office maintains Wu et al. teach use of antibodies to detect a target ligand and clearly anticipates claim 1.

Appellant has not put forth any argument traversing the individual limitations of claims 5 and 7. The Office maintains Wu et al. clearly anticipates claims 5 and 7 for the reasons set forth above.

(9.) Appellant states Wu et al. does not teach the claimed "depressions and/or protrusions". Claim 3 "... said surface is a textured surface comprising one or more depressions and/or protrusions extending between 1 nm and 0.5mm from the surface". The Office takes the position the nonporous surface taught by Wu et al. would have been expected to have **at least one depression or protrusion** from the surface in the

claimed range of 1nm to 0.5mm as an artefact of the manufacturing process. The Office maintains Wu et al. clearly anticipated pending claim 3.

(10.) Appellant states Wu et al. does not teach the claimed "... one or more of said particles are entrapped within depressions and/or between protrusions on the textured surface". As stated above, the Office expects the nonporous surface taught by Wu et al. to have at least one manufacturing artefact that clearly anticipates claim 3. Wu et al. teaches binding particles to the surface as discussed above. It would have been expected for at least one particle to be bound on the artefact. Wu et al. clearly anticipates claim 4.

(11.) Appellant states Findlay and Wu et al. fail to teach the limitations of claim 6 "... a second surface spaced at a capillary forming distance from said non-porous surface". The Office has addressed this issue in the new grounds of rejection under 35 USC 103.

#### **(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section (9) above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer

exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

Lyle A. Alexander

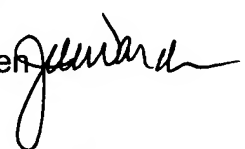


**LYLE A. ALEXANDER**  
**PRIMARY EXAMINER**

**A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:**

  
GREGORY MILLS  
QUALITY ASSURANCE SPECIALIST

Conferees:

Jill Warden 

  
Romulo Delmendo